

GRONEK & LATHAM, LLP

ATTORNEYS AT LAW

4552

00

NOV 17

18:56

DEBORAH B. ANSBRO
DAVID P. BARKER
MICHAEL J. BEAUDINE
BRIAN W. BENNETT
JOSEPH G. COLOMBO
DANIEL H. COULTOFF
ARISTIDES "KICO" J. DIAZ
MARIANE L. DORRIS

390 NORTH ORANGE AVENUE, SUITE 600
ORLANDO, FLORIDA 32801
POST OFFICE BOX 3353
ORLANDO, FLORIDA 32802
TELEPHONE: (407) 481-5800
FACSIMILE: (407) 481-5801

MICHAEL J. FURBUSH
ROBERT J. GRONEK
PETER G. LATHAM
K. RODNEY MAY
GREGORY W. MEIER
PAUL L. SANGIOVANNI
R. SCOTT SHUKER
KAREN K. WARD

CHRISTOPHER K. KAY
OF COUNSEL

WRITER'S DIRECT DIAL:
(407) 481-5830

November 17, 2000

Dockets Management Branch
HFA - 305
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: **DOCKET NO. 00N-1351: FOOD LABELING; USE OF THE TERM "FRESH" FOR
FOODS PROCESSED WITH ALTERNATIVE NON-THERMAL TECHNOLOGIES**

Dear Sir(s) and Madam(s):

This letter is submitted to you on behalf of our client, Citrus World, Inc., and supplements their response dated August 22, 2000. Citrus World, Inc. produces citrus and other fruit juices and drinks. As a cooperative, Citrus World, Inc. represents over one thousand citrus growers owning over 60,000 acres of citrus groves in the state of Florida. As detailed below, Citrus World, Inc. does not believe the use of the term "fresh" should be permitted in conjunction with juice subjected to the Alternative Non-Thermal Technologies.

1. Consumer Perception of the term "Fresh" and the definition under Section 21 C.F.R. §101.95.

Prior to 1993, FDA enforced labeling claims such as the use of the term "Fresh" or other claims under the general prohibition of "misbranding" or "mislabeling" without clarification by specific regulation. After increased use of the term on a number of food products resulted in increased consumer confusion, the FDA developed the current regulations, namely 21 C.F.R. §101.95. The FDA in 1993 concluded that because of the likelihood to mislead consumers the word "fresh" should not be used to imply a food product is "unprocessed" when, in fact, it has been processed. Citrus World, Inc.'s experience in the market and consumer group responses indicate

00N-1351

C 46

the process of "codifying" and enforcing this definition has strengthened consumer's reliance on the use of the term "fresh". We believe the result has created greater certainty in consumers' minds and greater value to the industry for the use of the term "fresh". It is also worth emphasizing that the definition ascribed to "fresh" through this process is based in large part upon consumer perception. In fact, consumer perception was referenced in the 1993 findings to validate revising the proposed definition and the phrase "in a manner that suggests or implies..." in §101.95(a) embodies consumer perception into the heart of the definition. It is also worth noting that most of the exceptions in §101.95(c) are also founded upon significant consumer awareness (e.g., milk, wax coating, etc.).

In addition to the clarity afforded by the existing definition of "fresh", the term has unique application to juices. Specifically, when applied to juices, "fresh" assumes fresh fruit is mechanically expressed in a similar manner as consumers could obtain if extracted at home on a kitchen appliance. Thus, the term means not only that the fruit was fresh but the process is simple extraction. We believe consumers rely upon "fresh" as applied to juice to mean much more than "organo-leptic characteristics". The exception in §101.95(c) afford no support for applying the term "fresh" to Alternative Non-Thermal Technologies applied to juice. The ability to utilize home extraction affords consumers a readily available means of supply and comparison. For example, in the case of citrus juice, it is estimated that more than five hundred million oranges are consumed annually as "at home" expressed juice in the United States. The FDA found in 1993 "The definition ["Fresh"] has particular applicability where there are processed and unprocessed forms of the food available."

Thus, we believe consumer perception should be the primary basis in analyzing Alternative Non-Thermal Technologies in the context of the use of the word "fresh". We believe consumers are generally unaware and uninformed of Alternative Non-Thermal Technologies and the effects of these processes. While technological advancement should be encouraged, it should not be promoted at the expense of the consumer's trust and reliance upon the FDA and its regulations, especially where the trust is founded upon a consumer based definition.

2. Are Alternative Non-thermal Technologies truly non-thermal?

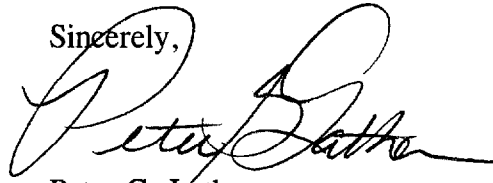
All indications are that a "shelf life extension" is achieved by processing fruit with Alternative Non-Thermal Technologies and we believe this will be seen as a "form of preservation". This is especially true given the fact that the Institute of Food Technologies (IFT) final report entitled "Kinetics of Microbial Inactivation for Alternative Food Processing Technologies" indicates that the temperature of the juice does rise when certain "non-thermal" processes are applied and that other significant questions concerning the effects of Alternative Non-Thermal Technologies require further research. Based upon the knowledge today, Alternative Non-Thermal Technologies processes are likely perceived as much closer to the modern "flash pasteurization" and would not be perceived as closer to "unprocessed". In fact,

many of the attributes claimed for Alternative Non-Thermal Technologies are capable of duplication with modern pasteurization.

3. What best describes alternative process.

As mentioned herein, we believe consumer perception would support some description of the processes described as "Alternative Non-Thermal Technologies" but would **not** permit the use of "fresh" or otherwise imply juices subjected to Alternative Non-Thermal Technologies are "fresh squeezed". One alternative to that is to utilize the term of "pasteurized" for the Alternative Non-Thermal Technologies (provided the research ultimately establishes the alternative process to have adequate safety enhancing effects on the juice). Our research indicates pasteurization is generally understood by consumers to involve a limited process primarily for health/safety benefits. Utilizing the term "pasteurized" could afford Alternative Non-Thermal Technologies a method of describing their product that is consistent with consumer perception. Those utilizing an Alternative Non-Thermal Technology described with the qualifier "pasteurized" can inform consumers of any perceived "enhancement" to the extent permissible under FDA regulations and existing laws.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter G. Latham", written in a cursive style.

Peter G. Latham

PGL:bs

cc: Dr. Robert C. Behr
Mr. Kevin Gaffney
Mr. Stephen M. Caruso

54
1000

FedEx USA Airbill FedEx Tracking Number

8169 4560 6429

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.
Date 11/17/00 **FedEx Tracking Number** 816945606429
Sender's Name Peter G Latham, Esq. **Phone** 407 481-5800
Company KAY GRONEK & LATHAM
Address 390 N ORANGE AVE STE 600
City ORLANDO **State** FL **ZIP** 32801
2 Your Internal Billing Reference 2901003 PCL
3 To Recipient's Name Dockets Management Branch
Company HRA.-305, Food and Drug
Address Administration Room 1001
City Rockville **State** MD **ZIP** 20852



0120587810

Form ID No. 0215 **Recipients Copy**

4a Express Package Service Packages up to 150 lbs. Delivery commitment may be later in some areas.
☒ **FedEx Priority Overnight** Next business morning ☐ **FedEx Standard Overnight** Next business afternoon ☐ **FedEx First Overnight** Earliest next business morning delivery to select locations
☐ **FedEx 2Day*** Second business day ☐ **FedEx Express Saver*** Third business day
4b Express Freight Service Packages over 150 lbs. Delivery commitment may be later in some areas.
☐ **FedEx 1Day Freight*** Next business day ☐ **FedEx 2Day Freight** Second business day ☐ **FedEx 3Day Freight** Third business day
5 Packaging *Declared value limit \$500
☒ **FedEx Letter*** ☐ **FedEx Pak*** ☐ **Other Pkg.** Includes FedEx Box, FedEx Tube, and customer pkg.
6 Special Handling
☐ **Saturday Delivery** Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes ☐ **Sunday Delivery** Available for FedEx Priority Overnight to select ZIP codes ☐ **HOLD Weekday at FedEx Location** Not available with FedEx First Overnight ☐ **HOLD Saturday at FedEx Location** Available for FedEx Priority Overnight and FedEx 2Day to select locations
Does this shipment contain dangerous goods? One box must be checked
☐ **No** ☐ **Yes** As per attached Shipper's Declaration ☐ **Yes** Shipper's Declaration not required ☐ **Dry Ice** Dry Ice, 9 UN 1845 x kg
☐ **Cargo Aircraft Only**
7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below ☐ **Obtain Recip. Acct. No.**
☐ **Sender** Acct. No. in Section 1 will be billed ☐ **Recipient** ☐ **Third Party** ☐ **Credit Card** ☐ **Cash/Check**
Total Packages **Total Weight** **Total Charges**
*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.
Questions? Call 1-800-Go-FedEx (800-463-3339)
Visit our Web site at www.fedex.com
SRS 999 Rev. Date 11/98 Part #154813S ©1994-98 FedEx PRINTED IN U.S.A.

359